Evaluation of Granted USPTO Claims of GTA Effects for Registered Pesticides in Combination

CLA Work Group
August 20, 2018

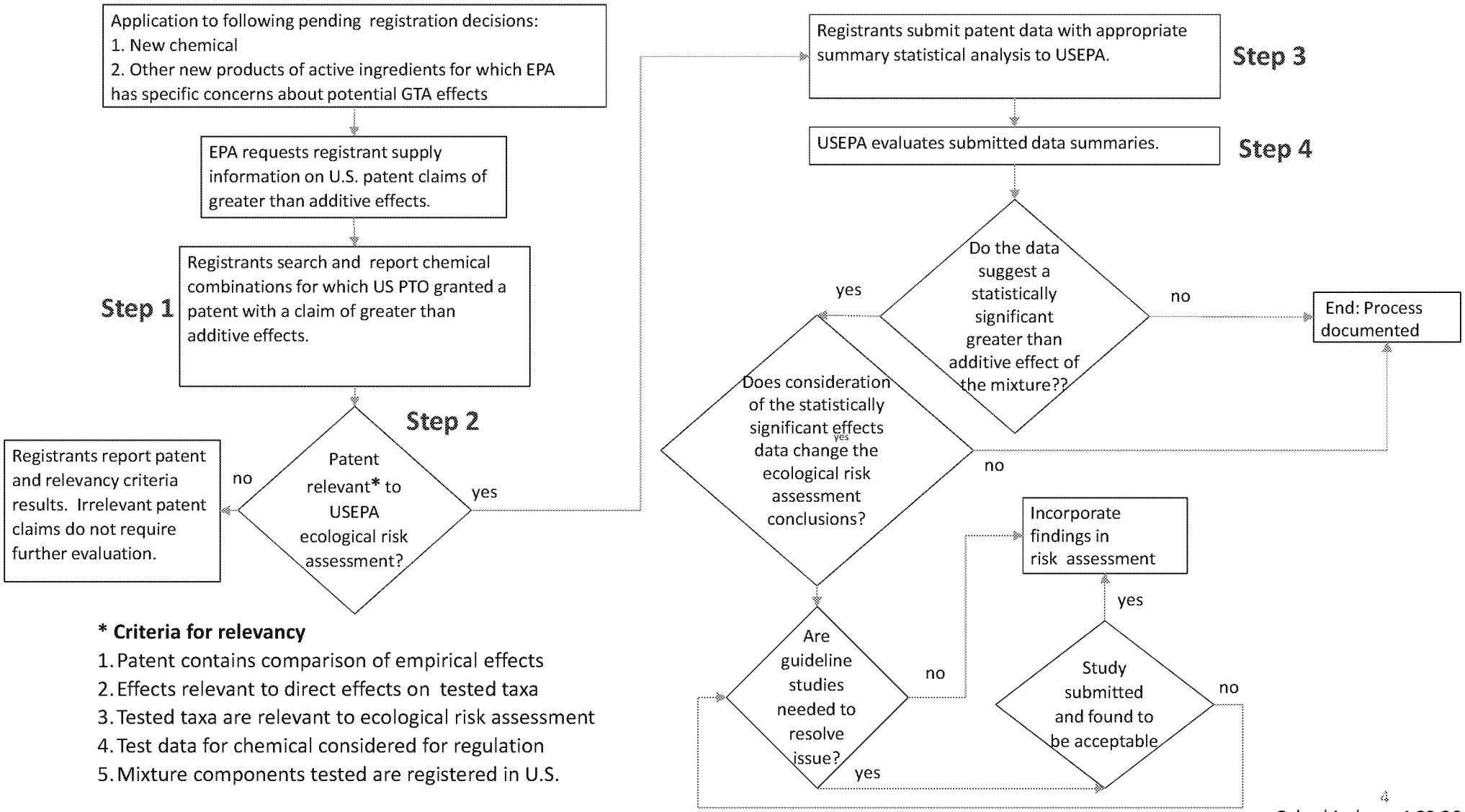
Driver for the Meeting

- Work with the Agency to further improve the existing USPTO granted patent review process with the goal to:
  - Minimize burden on the Agency at a time of resource limitations and expedite regulatory decision making.
  - Continue to document that the granted patent evaluation process has been performed.
  - Expedite approval of tank mixes that are vital for resistance management programs.

- Longer-term work with the Agency to design a "**project**" that will inform a determination of whether continued review of granted USPTO patents with GTA claims impacts EFED assessments.

EPA's Decision Framework is Amenable for Documenting the Evaluation Process

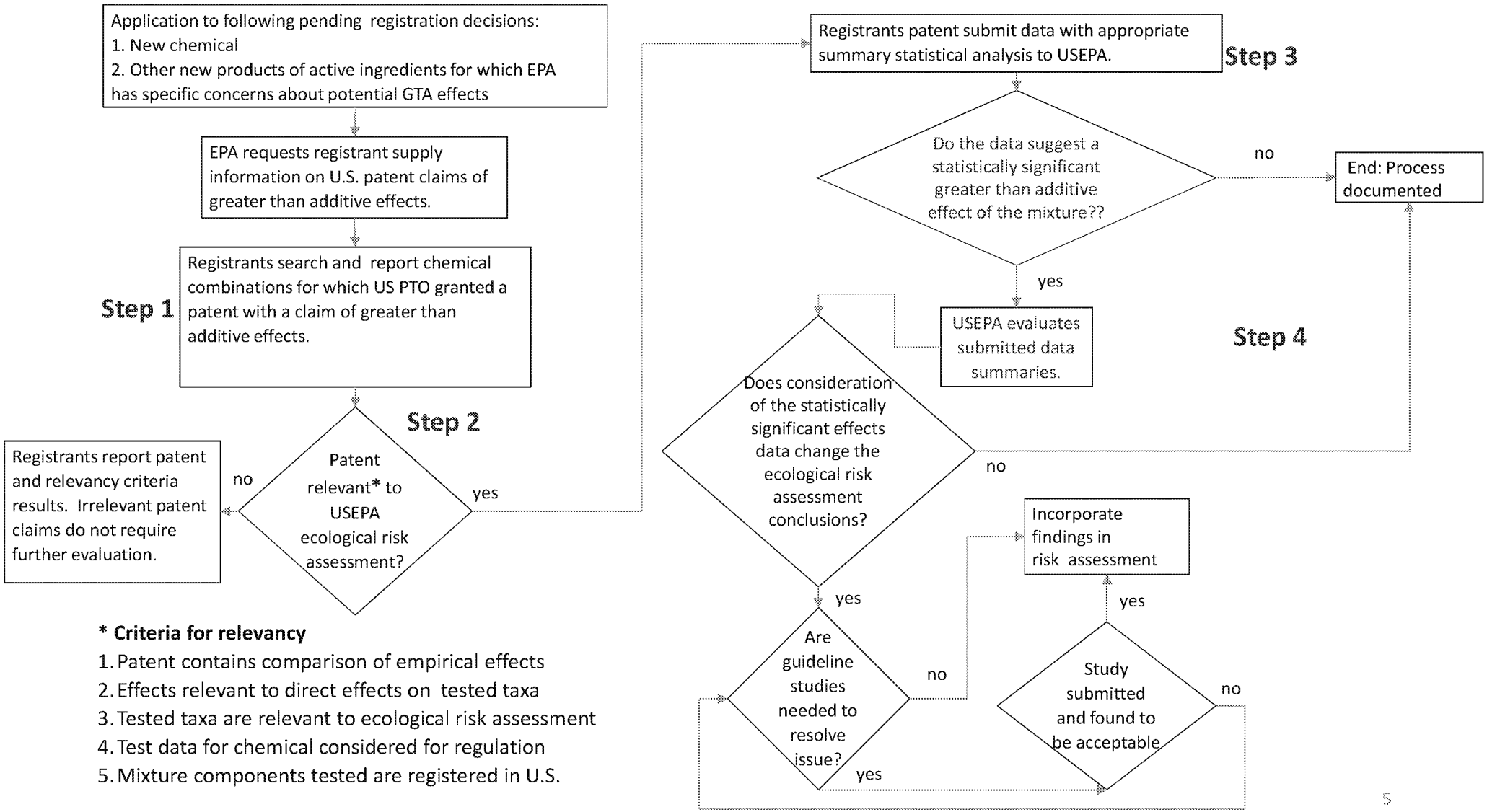
- EPA's existing decision framework (slide 4) with slight modification (slide 5) is amenable for documenting the evaluation process for USPTO granted patents with GTA claims.
- Permitting self-certification for granted GTA claims that do not meet the requirements of steps 1, 2 or 3 of EPA's decision framework.
- An example where the Agency uses a self-certification process is bridging droplet data from wind tunnel studies.



*** Criteria for relevancy**

1. Patent contains comparison of empirical effects
2. Effects relevant to direct effects on tested taxa
3. Tested taxa are relevant to ecological risk assessment
4. Test data for chemical considered for regulation
5. Mixture components tested are registered in U.S.

Odenkirchen, ACS 2017



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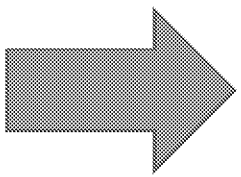
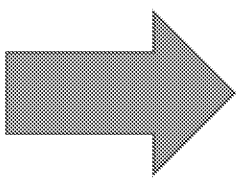
Proposal for Self-Certification with EPA Framework

- **STEP 1:** Registrants search for and report chemical combinations for which USPTO granted a patent for an application with a claim of GTA effects.



  - Registrant self-certify when no granted US PTO patents with a claim of GTA effects are identified.
  - The registrants will submit documentation summarizing the search methodology and results of the search to document the process.

- **STEP 2:** If a granted US patent with a claim of GTA effects is identified in the search, a determination is made whether the Patent is relevant to an EPA ERA using EPA's interim relevancy criteria.



  - Registrant self-certify when no granted USPTO patents with a claim of GTA are determined to be relevant based on EPA's interim relevancy criteria.
  - The registrant documents and submits the search methodology, results of the search and the assessment used to determine the lack of relevancy for each patent with a claim of GTA effects.

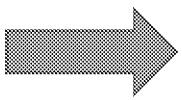
Example Table Documenting Assessment with EPA Relevance Criteria

EPA Relevance Criteria	Yes	No
Patent contains comparison of empirical effects?	✓	
Effects relevant to direct effects on tested taxa?	✓	
Tested taxa are relevant to ecological risk assessment?		✓
Mixture components tested are registered in U.S.?	✓	
Test data for chemical considered for regulation?	✓	

A "No" for any criteria makes the GTA claim irrelevant for an EFED ERA and the process stops at Step 2

Proposal for Self-Certification with EPA Framework

- STEP 3: Registrant performs a statistical analysis, comparing observed and predicted values, of the relevant data in the granted claim of GTA effects.



- Registrant self-certify when the outcome of the statistical analysis of relevant data claiming GTA is not statistically significant using the EPA analysis procedure(s).
- The registrant documents and submits the search methodology, results of the search and results of the statistical analysis that determined the granted claim of GTA is not statistically significant.

The registrant cannot self-certify when there are statistically significant GTA effects and a secondary analyses of the data is required to interpret the data in a risk assessment and/or risk management context.

Example Table Documenting Assessment with EPA Relevance Criteria

EPA Relevance Criteria	Yes	No
Patent contains comparison of empirical effects?	✓	
Effects relevant to direct effects on tested taxa?	✓	
Tested taxa are relevant to ecological risk assessment?	✓	
Mixture components tested are registered in U.S.?	✓	
Test data for chemical considered for regulation?	✓	
Is the GTA statistically significant?		✓

A "No" for statistical significance makes the GTA claim irrelevant for an EFED ERA and the process stops at Step 3

Example Documenting Individual Combinations for GTA

RAW DATA INPUT				
	REPLICATE	Chem A Response	Chem B Response	Observed Combined Response
RATES		15 g/ha	150 g/ha	15+150
	1	0.8	0.75	1
	2	0.9	0.7	1
	3	0.8	0.75	0.95
	4	0.9	0.7	1

SELECTED INTERIM CALCULATIONS					
		Chem A	Chem B	Observed Combined Response	Predicted Additive Response
RATES		15 g/ha	150 g/ha	15+150	15+150
CALCULATIONS	mean	0.85	0.725	0.9875	0.9588
	variance	0.0033	0.00083	0.00063	0.00063
	N	4	4	4	

STATISTICAL ANALYSIS		
t-value	df	p-value
2.18	3.64	0.058

CONCLUSION: Self certification allowed - insufficient evidence to conclude statistically "GTA effects" using an α-level of 0.05

Submitted Documentation for Self-Certification

- **Documentation would include:**
  - A summary of the systematic patent search methodology and outcome of the search (step 1).
  - A summary of the evaluation of patents claiming GTA using the interim EPA relevance criteria (step 2).
  - A summary of statistical evaluation, using EPA's Excel sheet, showing no significant GTA combinations (step 3).

Long-term Project to Assess Impact of GTA Claims on EFED Assessments

- **Objective:** Do granted claims with statistically significant GTA impact EFED's current FIFRA ERAs?

- Proposed approach:
  - First, define the number of active ingredients to evaluate with an appropriate level of statistical confidence to support the conclusions.
  - Use coded names for the active ingredients and mixing partners.
  - Evaluate whether GTA claims that pass the relevancy criteria AND have statistically significant GTA effects have any utility to impact EFED's ecological risk assessments.
  - Provide a report to EPA summarizing and concluding the outcome of the project.

Discussion and Next Steps

- Feedback on the proposal to move to self-certification for patents that do not go beyond step 3 of EPA's decision framework.

- Feedback on the scope and nature of a project to assess the potential impact of granted claims of GTA on ERAs.

Feedback